

THE OFFICE ACTION

Applicants have now had an opportunity to carefully consider the Examiner's comments set forth in the final Office Action of October 28, 2004.

In the Office Action, Claim 42 was rejected under 35 U.S.C. §101 because the claimed invention was said to be directed to non-statutory subject matter.

Claims 3, 5, 24 and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Caro (WO 95/09585) ("Caro").

Claim 42 was rejected under 35 U.S.C. §102(b) as also being anticipated by Caro.

Claims 6 and 26-30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Caro in view U.S. Patent No. 5,697,971 to Fischell et al ("Fischell").

Claim 31 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Caro and Fischell and further in view of U.S. Patent No. 5,104,404 to Wolff ("Wolff").

Claims 12-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Caro and Fischell and further in view of U.S. Patent No. 6,015,387 to Schwartz et al ("Schwartz").

In this response, Applicants have responded to the Office Action and present remarks believed to address the Examiner's rejections and argue that the claims presented herewith are in condition for allowance over the art of record.

Continued examination is respectfully requested.

REMARKS

I. Claim Rejections - 35 U.S.C. §101

With respect to **claim 42**, the Examiner stated that the claim language claims a combination of a stent with a naturally occurring article (i.e. an intact vessel), and for this reason, the claim is considered non-statutory. Applicants have amended the claim to refer to an "associated" intact vessel. It is believed that such amendment addresses the Examiner's §101 rejection.

II. Claim Rejections Under 35 U.S.C. §102(b)

With respect to independent **claim 24**, as amended, Applicants respectfully submit that the subject matter claims differs from the art taught in Caro.

Specifically, claim 24 has been amended to include a stent having a supporting portion which comprises a hollow tube, the walls of which have openings therein so that

the interior of a vessel part is not fully shielded (see page 5, lines 8-10 of the present application). The interior wall of a vessel comprises living cells, which need to receive a supply of nutrients from the blood flowing in the vessel and also needs to excrete waste products into the blood (known in the art as "mass transport"). The provision of openings in the walls of a stent is a known feature of conventional stents and is important because openings allow this "mass transport." If a stent having solid walls was placed inside a vessel, then this "mass transport" could not occur because the vessel wall would not be in contact with the blood flow. This would cause damage to the cells of the vessel wall. As such, openings in the walls of the stent are provided to avoid this problem.

Applicants respectfully submit that by providing openings in the walls of the stent of the present invention, the interior of the vessel is not fully shielded and an additional benefit in relation to swirl flow is induced by the stent. The stent of the present invention allows the vessel wall to be exposed to the swirl flow via the openings so that the vessel wall experiences relatively high wall shear stress. Further, the vessel wall can experience a relatively uniform distribution of wall shear (see page 12 lines 16-20 of the present application). The benefits of having uniform wall shear and avoiding low wall shear are well explained in the present application. For example, it is noted that the "local flow pattern in blood vessels (including wall shear) markedly influences their biology and, it appears, the development of vascular disease" (see page 11 lines 15-17 of the present application). It is further stated that "for example, altherosderosis appears to develop preferentially at locations in arteries where the wall shear is on average low and/or there are large oscillations of wall shear" (see page 11 lines 18-20 of the present application).

Thus, cells of the vessel wall benefit from being subjected to shear stress, which helps to keep the cells healthy. Such mechanical stress is generated by near wall blood flow in the vessel. By using a stent which induces swirl flow, in accordance with the present invention, a relatively uniform distribution of wall shear is obtained (see page 12, lines 16-20 of the present application) with the consequent avoidance or minimizing of low wall shear regions. If on the other hand a stent having solid walls was placed within a vessel, the interior of the vessel would be fully shielded and not subjected to the favorable swirl flow and the resulting shear stress. This would increase the risk of the development of vascular disease, such disease being avoided by the stent of the

present invention having openings in the walls so that the vessel wall cells are not shielded from the flow and are subject to the desirable shear stress.

Conversely, Caro discloses a tubing made of a suitable biocompatible material wherein a stent can be used "internally, externally or integral to the wall of the tubing" (see page 6, lines 9, 10 of Caro). The tubing of Caro, with or without a supporting stent, is used as a vascular prosthesis (see the title, the claims, and page 5, lines 28-32 of Caro). There is no disclosure of a combination of the Caro hollow prosthesis tubing and a stent ("the stented tubing") having openings in its walls. Therefore, if this stented tubing were used as a stent in a vessel, then the interior of the vessel would be fully shielded since the walls of the stented tubing would not have openings therein. Applicants submit that there is no basis whatsoever in Caro for concluding that the stented tubing would be capable of the use proposed by the present invention. In the absence of a clear disclosure of this capability, the Examiner's anticipation rejection is not justified.

With regard to the inventiveness of amended claim 24, there is no suggestion whatsoever in Caro that the stented tubing (prosthesis) could or should be used as a stent within an intact vessel. Further, even if it was, it would not meet the limitations of claim 24 which now requires that the stent has openings in the walls so that the vessel is not fully shielded. There is simply no suggestion in Caro that the prosthesis could have such openings in the walls. In fact, the prosthesis would not achieve its purpose if it did because it would leak. Thus, Applicants respectfully submit that claim 24, as amended, is also clearly inventive over Caro.

Applicants further disagree with the Examiner's opinion that the stented tubing of Caro as a whole could be used as a stent within an intact vessel. In addition, in the event the Examiner should take the view that the stent of Caro could be taken separately, Applicants submit that there is no disclosure whatsoever that the tubing and stent could be separated such that the stent alone could be used to support an intact vessel. Any argument that the stent of Caro could indeed be used in such a fashion would be based purely on hindsight. Caro simply discloses that a stent can be used with a tubing (prosthesis) having a non-planar curvature in order to prevent collapse or kinking of the tubing. Applicants acknowledge that the stent of Caro could be a known stent, such as that disclosed in Fischell having holes therein. However, there is no disclosure that the stent, prior to insertion in the tubing would itself have a non-planar

curvature. Thus, it would not be suitable for imposing a non-planar curve on a vessel as claimed in claim 24.

It is respectfully submitted that the Examiner's interpretation of Caro (or the claim limitations of the pending claims) is strained and not a fair interpretation. Accordingly, for the reasons set forth above, Caro, whether it is considered on its own under §§102 or 103, or in combination with any of the remaining art of record, fails to teach or suggest all the claim limitations of independent amended claim 24, and, consequently, claims 3, 5, 6, 12-16, and 25-31 dependent or ultimately dependent from claim 24.

With regard to independent **claim 42**, this claim further strengthens Applicants' position regarding novelty. As recited in claim 42, the stent is inserted into an associated intact vessel. Contrary to the Examiner's suggestion, such a stent, placed within an associated intact vessel, is entirely different from the stented tubing used as a prosthesis, as disclosed in Caro. Caro simply does not disclose a stent in place in an intact vessel. Accordingly, Caro fails to teach or suggest all the claim limitations of independent amended claim 42.

III. The Rejection of Claims 6 and 26-30 under 35 U.S.C. §103(a)

For the reasons set forth above, the references cited by the Examiner fail to teach or suggest all the claim limitations of independent claim 24, as amended, and, consequently, claims dependent or ultimately dependent from claim 24. For at least this reason, the cited references do not render claims 6 and 26-30 dependent therefrom obvious.

IV. The Rejection of Claim 31 under 35 U.S.C. §103(a)

For the reasons set forth above, the references cited by the Examiner fail to teach or suggest all the claim limitations of independent claim 24, as amended, and, consequently, claims dependent or ultimately dependent from claim 24. For at least this reason, the cited references do not render claim 31 dependent therefrom obvious.

V. The Rejection of Claims 12-16 under 35 U.S.C. §103(a)

For the reasons set forth above, the references cited by the Examiner fail to teach or suggest all the claim limitations of independent claim 24, as amended, and, consequently, claims dependent or ultimately dependent from claim 24. For at least this reason, the cited references do not render claims 12-16 dependent therefrom obvious.

VI. New Claim 43

Regarding new independent claim 43, this claim again further strengthens Applicants' position regarding novelty. Claim 43 recites a method of inserting a stent having a supporting portion into an associated intact vessel such that part of the associated intact vessel is disposed around the supporting portion so that the stent internally supports the associated vessel part. Such a method of placing a stent within an intact vessel is entirely different from the stented tubing used as a prosthesis, as disclosed in Caro. Again, Caro simply does not disclose a stent in place in an intact vessel. As such, Caro, whether it is considered on its own under §§102 or 103, or in combination with any of the remaining art of record, fails to teach or suggest all the claim limitations of new independent claim 43.

CONCLUSION

For the reasons detailed above, it is respectfully submitted that all claims remaining in the application (Claims 3, 5, 6, 12-16, 24-31, 42 and 43) are now in condition for allowance. The foregoing comments do not require unnecessary additional search or examination.

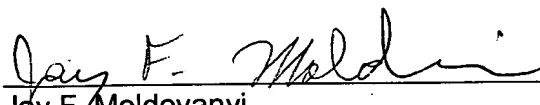
No additional fee is believed to be required for this Amendment. If, however, a fee is due, the Commissioner is authorized to charge our Deposit Account No. 06-0308.

In the event the Examiner believes a telephone call would expedite prosecution, he is invited to call the undersigned.

Respectfully submitted,

FAY, SHARPE, FAGAN,
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28 Jan 2005
Date

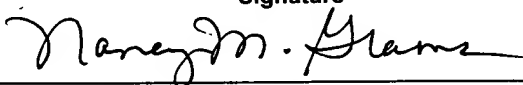

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